**UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF MICHIGAN**
**SOUTHERN DIVISION**

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| Association of American Physicians & Surgeons,<br><br>Plaintiff,<br>v.<br><br>Food & Drug Administration, et al.,<br><br>Defendants. | Case No. 1:20-cv-493-RJJ-SJB |

**Combined Memorandum in Support of Defendants' Motion to Dismiss and in Opposition to Plaintiff's Motion for a Preliminary Injunction**

OF COUNSEL:

ROBERT P. CHARROW
General Counsel

STACY CLINE AMIN
Deputy General Counsel
U.S. Department of Health
and Human Services

Chief Counsel
Food and Drug Administration

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation

SAMANTHA HONG
SUSAN WILLIAMS
Associate Chief Counsel
Office of the General Counsel
Food and Drug Division
10903 New Hampshire Avenue
Silver Spring, MD 20993

ETHAN P. DAVIS
Acting Assistant Attorney General

MICHAEL D. GRANSTON
Deputy Assistant Attorney General
Civil Division

GUSTAV W. EYLER
Director

ANDREW E. CLARK
Assistant Director

JAMES W. HARLOW
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386
(202) 514-6786
(202) 514-8742 (fax)
James.W.Harlow@usdoj.gov

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## INTRODUCTION

Plaintiff Association of American Physicians & Surgeons ("AAPS") sues the U.S. Department of Health and Human Services ("HHS") for supposedly impeding "the ability of President Donald Trump to make available to the public" the drug hydroxychloroquine sulfate ("hydroxychloroquine"). But this sort of generalized grievance is not a case or controversy under Article III, leaving AAPS without standing. And the only concrete agency action challenged in the complaint was revoked, mooting this case. Even if AAPS could overcome these jurisdictional obstacles, the complaint fails to state a claim for relief. This case must be dismissed.

The drug hydroxychloroquine is approved by the U.S. Food and Drug Administration ("FDA") for the treatment of malaria, lupus, and rheumatoid arthritis. Amidst the COVID-19 pandemic, some evidence indicated the drug may be a potential treatment for COVID-19 (a condition for which the drug is not approved). And HHS accepted donations of hydroxychloroquine from drug manufacturers into the Strategic National Stockpile, a supply of drugs and other medical supplies maintained by HHS to respond to public health emergencies.

Pursuant to its statutory authority, FDA issued an emergency use authorization ("EUA") for hydroxychloroquine distributed from the Stockpile to public health authorities for use in certain hospitalized COVID-19 patients. FDA determined that, based on the scientific evidence available at that time, it was reasonable to believe that the drug may be effective in treating COVID-19 and the drug's potential benefits outweighed the potential risks for that population. Notably, the EUA did *not* govern the drug's general commercial availability.

Since the complaint in this case was filed, however, FDA revoked the EUA for hydroxychloroquine because new scientific evidence about the drug's use in COVID-19 patients changed the agency's evaluation of the risks and benefits. FDA could no longer

conclude that the potential benefits of use in hospitalized patients outweighed the known and potential risks of that use. Nonetheless, the drug remains approved for treating malaria, lupus, and rheumatoid arthritis, and is commercially available.

AAPS objects to the EUA's parameters as unduly limited and to HHS's failure to publicly distribute the Stockpile's supply of hydroxychloroquine. But no matter how sincere the objection, this case must be dismissed for several reasons.

*First*, AAPS lacks standing because it raises nothing more than a generalized grievance about a federal policy in response to the COVID-19 pandemic. The group's claim to standing depends entirely upon that of an anonymous Dr. John Doe. But Dr. Doe cannot establish a legal interest in medical supplies maintained in the Stockpile—let alone an injury-in-fact traceable to any action by HHS. Dr. Doe and therefore AAPS cannot satisfy the constitutional minimum threshold for standing.

*Second*, apart from the lack of standing, the case is now moot. The only final agency action challenged in the complaint—the EUA—has been revoked and AAPS chose not to amend. By failing to account for that significant change in facts, a live case or controversy no longer exists (not that it ever did) for the Court to adjudicate.

*Third*, AAPS fails to state a claim upon which relief can be granted. Its Administrative Procedure Act ("APA") claim fails because Congress committed decisions related to EUAs to agency discretion and FDA acted within its statutory authority. AAPS's First Amendment freedom of association claim and its Fifth Amendment equal protection claim are neither factually well-pleaded nor legally well-grounded.

*Finally*, even if this Court declines to dismiss the complaint, AAPS is still not entitled to the extraordinary relief of a preliminary injunction. AAPS has no right to force the deployment of supplies in the Stockpile for private ends and this Court has no cause to interfere with decisions of public health officials and scientists responding to COVID-19.

## BACKGROUND

### I. HHS has broad discretionary authority to respond to public health emergencies.

Over the last two decades, Congress built a statutory infrastructure to address and respond to public health emergencies, such as the current COVID-19 pandemic. Two particular statutory programs are relevant to this case, both of which afford HHS significant discretionary authority to rapidly respond to public health emergencies.

#### A. Emergency Use Authorizations

Under the Federal Food, Drug, and Cosmetic Act, FDA approval is required "before a 'new drug' may be lawfully marketed." *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 613 (1973); *see* 21 U.S.C. § 355(a). FDA does not approve a drug *in toto*. Rather, manufacturers must submit evidence that a drug is safe and effective for use under the conditions prescribed on the proposed label. *Hynson*, 412 U.S. at 617; *see* 21 U.S.C. § 355(b).[1] If FDA determines that the evidence is sufficient, the agency approves the drug as safe and effective under the specific conditions of use set forth on the label. *See* 21 U.S.C. § 355(d).

In certain cases of "an actual or potential emergency"—including, for instance, a public health emergency affecting U.S. citizens abroad or a domestic emergency involving biological, chemical, radiological, or nuclear agents—Congress empowered HHS to authorize the introduction into interstate commerce of drugs (and other FDA-regulated products) "intended for use" to respond to the emergency. 21 U.S.C. § 360bbb-3. Specifically, FDA may authorize the emergency use of unapproved drugs

[1] AAPS repeatedly misstates this standard, claiming that "safety is determined with respect to patients, not diseases." Compl., ECF No. 1, PageID.16. The statute, however, expressly limits determinations of safety and effectiveness to the conditions of use on the proposed label, including the diseases the drug purports to treat. 21 U.S.C. § 355(b). A simple example illustrates this point. A chemotherapy drug may be very toxic, but it is considered safe for use in the treatment of various cancers. It would not be considered safe to treat a simple headache.

(and other unapproved FDA-regulated products) or approved drugs or medical devices for unapproved uses for the duration of the emergency. *Id.* § 360bbb-3(a)(1)-(2).

The EUA issuance process reflects the rapid response required to domestic, military, or public health emergencies. The HHS Secretary first must declare that circumstances exist justifying an EUA based on a required determination of threat. *See id.* § 360bbb-3(b). FDA then may issue an EUA if the agency concludes that certain statutory criteria are met. FDA must determine, "based on the totality of scientific evidence available . . . including data from adequate and well-controlled clinical trials, if available," that (1) the product to be authorized by the EUA "may be effective in diagnosing, treating, or preventing" a serious or life-threatening disease or condition, (2) "the known and potential benefits of the product . . . outweigh the known and potential risks," and (3) there is "no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating" the disease or condition. *See id.* § 360bbb-3(c).

When issuing an EUA, FDA also may impose any "conditions on an authorization . . . necessary or appropriate to protect the public health." *Id.* § 360bbb-3(e)(1)(B), (e)(2)(A). "[T]he circumstances and the appropriateness of an" EUA must be "periodically review[ed]." *Id.* § 360bbb-3(g)(1). If the issuance criteria are no longer satisfied or FDA determines that protection of public health or safety warrants it, the EUA may be revised or revoked. *Id.* § 360bbb-3(g)(2). Finally, Congress expressly declared that all "[a]ctions under the authority of this section . . . are committed to agency discretion." *Id.* § 360bbb-3(i).

**B. Strategic National Stockpile**

Another core component of the federal government's ability to respond to public health emergencies is the Stockpile. Congress established the Stockpile "to provide for and optimize the emergency health security of the United States . . . in the event of a . . .

public health emergency." 42 U.S.C. § 247d-6b(a)(1). The Stockpile comprises "drugs, vaccines and other biological products, medical devices, and other supplies," such as personal protective equipment. *Id.* It is maintained by the HHS Secretary "in collaboration with the Assistant Secretary for Preparedness and Response and the Director of the Centers for Disease Control and Prevention, and in coordination with the Secretary of Homeland Security." *Id.*

Among other responsibilities, HHS must regularly "review and revise, as appropriate" the Stockpile's contents "to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered" and to avoid depletion of current countermeasures. *Id.* § 247d-6b(a)(3)(D). Decisions about how to deploy the Stockpile are committed to "the discretion of" HHS "to respond to an actual or potential public health emergency or other situation in which deployment is necessary to protect the public health or safety." *Id.* § 247d-6b(a)(3)(G). No statutory right exists for private individuals to requisition supplies from the Stockpile.

## II. Hydroxychloroquine and HHS's Response to COVID-19

On February 4, 2020, the HHS Secretary determined, pursuant to 21 U.S.C. § 360bbb-3, that a public health emergency involving COVID-19 "has a significant potential to affect national security or the health and security of United States citizens living abroad." Determination of Public Health Emergency, 85 Fed. Reg. 7316, 7317 (Feb. 7, 2020). On March 27, 2020, building on the February 4th determination, the Secretary declared that circumstances justified "the authorization of emergency use of drugs and biological products during the COVID-19 pandemic." Emergency Use Authorization Declaration, 85 Fed. Reg. 18,250, 18,250-51 (Apr. 1, 2020).

### A. FDA issues the Hydroxychloroquine EUA.

Hydroxychloroquine is approved by FDA as a prophylaxis against and treatment for malaria, and for treatment of lupus and rheumatoid arthritis; it is not approved to

treat COVID-19. EUA, ECF No. 9-6, PageID.475.[2] Early and limited data, however, indicated that hydroxychloroquine might be effective against COVID-19. *Id.*

On March 28, 2020, FDA determined that the criteria for issuing an EUA for hydroxychloroquine were met. "Based on the totality of scientific evidence available" to FDA at that time, the agency found reason to believe that under certain limitations, hydroxychloroquine "may be effective in treating COVID-19" and the drug's "known and potential benefits . . . when used to treat COVID-19 outweigh the known and potential risks" of use in certain hospitalized patients. *Id.*, PageID.476; *see id.* (finding other criteria satisfied).

One limitation specified that hydroxychloroquine was authorized for use only when "administered by a healthcare provider pursuant to a valid . . . prescription of a licensed practitioner" for use "to treat adult and adolescent patients who weigh 50 kg [approximately 110 pounds] or more hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible." *Id.*, PageID.477; *see* 21 U.S.C. § 360bbb-3(d)-(e) (authorizing FDA to, among other things, establish conditions it "finds necessary or appropriate to protect the public health" regarding "the categories of individuals to whom, and the circumstances under which, the product may be administered with respect to such use"). Because of the limited data demonstrating hydroxychloroquine's effectiveness, FDA "encourage[d] the conduct and participation in randomized controlled clinical trials that may produce evidence concerning the effectiveness of [the drug] in treating COVID-19." EUA, PageID.475.

Another key limitation cabined the EUA's coverage only to hydroxychloroquine "distributed from the [Stockpile] to public health authorities for response to the COVID-

[2] The EUA is referenced in the complaint and therefore may be considered for purposes of a motion to dismiss. *Greenberg v. Life Ins. Co. of Va.*, 177 F.3d 507, 514 (6th Cir. 1999). The EUA also authorized chloroquine phosphate, an unapproved drug, for the same use. Because AAPS does not seek relief related to chloroquine phosphate, this brief discusses the EUA only as it applied to hydroxychloroquine.

19 pandemic." EUA, PageID.477; *see id.*, PageID.474 n.2 (defining "public health authority"). The EUA did *not* encompass commercial supplies of the drug.

**B. The Stockpile receives and distributes hydroxychloroquine under the EUA.**

The day after FDA issued the EUA, HHS announced receipt of hydroxychloroquine donated "for possible use in treating patients hospitalized with COVID-19 or for use in clinical trials." Press Release, HHS, *HHS accepts donations of medicine to Strategic National Stockpile as possible treatments for COVID-19 patients* (Mar. 29, 2020), ("HHS Donation Press Release");[3] *see* 42 U.S.C. § 238 (authorizing HHS Secretary "to accept on behalf of the United States gifts" for the benefit of the United States Public Health Service including those of tangible property). The donations were placed in the Stockpile, which "does not regularly stock" hydroxychloroquine, for eventual shipment to states. HHS Donation Press Release, *supra*.

By May 2020, the Stockpile had distributed more than 2 million courses of hydroxychloroquine treatment "to State and local health authorities." EUA Revocation, ECF No. 9-4, PageID.379. The drug also remained commercially available.

**C. FDA revokes the EUA.**

After issuance, FDA continued to evaluate "the circumstances and the appropriateness of" the EUA. 21 U.S.C. § 360bbb-3(g)(1). On June 15, 2020, "FDA's ongoing assessment" resulted in the EUA's revocation. EUA Revocation, PageID.381.

As the agency explained, "FDA scientific staff conducted reviews of . . . new data and also conducted new analyses of information known at the time of initial authorization." *Id.*, PageID.371. These reviews analyzed published studies, the National Institutes of Health's newly-issued COVID-19 treatment guidelines, and preliminary results from clinical trials involving hydroxychloroquine. *See id.*, PageID.373-81

[3] https://www.hhs.gov/about/news/2020/03/29/hhs-accepts-donations-of-medicine-to-strategic-national-stockpile-as-possible-treatments-for-covid-19-patients.html (last revised Apr. 6, 2020).

(explaining analysis). Ultimately, FDA concluded, among other things, that it was not reasonable to believe "the known and potential benefits of" hydroxychloroquine "outweigh the[] known and potential risks." *Id.*, PageID.369. Accordingly, FDA revoked the EUA. *See id.*; *see also* 21 U.S.C. § 360bbb-3(g)(2) (permitting revocation if agency determines the issuance criteria are no longer satisfied).

### III. AAPS challenges the EUA and demands hydroxychloroquine from the Stockpile.

On June 2, 2020, AAPS filed this suit to secure "timely access to hydroxychloroquine . . . , which has been donated in large quantities to the federal government for prompt distribution" and blamed government officials for supposedly acting "contrary to the wishes of President Donald Trump." Compl., PageID.1-2. Specifically, AAPS challenged the EUA's limitations on which patients were eligible to receive hydroxychloroquine from the Stockpile. *See id.*, PageID.15, 19.

AAPS asserts claims based on (1) the APA, (2) freedom of association under the First Amendment, and (3) equal protection under the Fifth Amendment. *See id.*, PageID.19-23. The group seeks sweeping declaratory and injunctive relief, including an order that HHS "make available and distribute promptly, and for the benefit of the public holding valid prescriptions, the [hydroxychloroquine] being stored in the" Stockpile and an injunction against "impeding the distribution, sale or purchase of [hydroxychloroquine] by adult members of the public during the COVID-19 pandemic." *Id.*, PageID.23-24.

Less than two weeks after AAPS sued, FDA revoked the EUA. Yet AAPS did not amend its complaint to address the fact that the agency action it challenged no longer existed.

Instead, on June 22, 2020, AAPS filed a motion for a preliminary injunction, reiterating that it had sued to assist "President Donald Trump to make [hydroxychloroquine] available to the public." PI Mem., ECF No. 9, PageID.295. It seeks

to obtain immediately much of the same relief ultimately sought in the complaint, including public distribution of hydroxychloroquine from the Stockpile. *See* PI Mot., ECF No. 8, PageID.67-68. Additionally, AAPS demands that HHS and FDA retract what the group characterizes as "disparaging statements made on June 16, 2020" about hydroxychloroquine. *Id.*, PageID.67.

The Government opposes AAPS's motion for extraordinary relief and moves to dismiss the case pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6).

## LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(1), the Court "presume[s]" to "lack jurisdiction" unless AAPS meets its "burden of establishing it." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006) (quotation omitted). In particular at the pleading stage, AAPS "must clearly allege . . . facts demonstrating each element" of standing to invoke this Court's jurisdiction. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (quotation omitted). If a suit becomes moot after filing, there is no longer a case or controversy under Article III. *See DaimlerChrysler*, 547 U.S. at 352.

Under Rule 12(b)(6), the Court must dismiss the complaint unless AAPS has "state[d] a plausible claim for relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. In scrutinizing the sufficiency of the complaint's allegations, the Court need not "accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain*, 478 U.S. 265, 286 (1986).

As for AAPS's motion for a preliminary injunction, it must show entitlement to such an "extraordinary remedy." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). AAPS "must establish that [it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest." *Id.* at 20; *see*

*Bays v. City of Fairborn*, 668 F.3d 814, 818–19 (6th Cir. 2012). A request for extraordinary relief must be denied when the movant cannot "*by a clear showing*, carr[y] the burden of persuasion." *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (emphasis in original).

## ARGUMENT

### I. This case must be dismissed for lack of standing.

Before all else, AAPS must establish its standing to bring this suit. *Sierra Club v. U.S. EPA*, 793 F.3d 656, 661 (6th Cir. 2015). Rooted in Article III's extension of the judicial power only to cases and controversies, the standing "doctrine limits the category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong." *Spokeo*, 136 S. Ct. at 1547. Because "[s]tanding is not dispensed in gross," *Davis v. Fed. Election Comm'n*, 554 U.S. 724, 734 (2008) (quotation omitted), AAPS "must demonstrate standing for each claim [it] seeks to press" and "each form of relief sought," *DaimlerChrysler*, 547 U.S. at 352; *see Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) ("The party invoking federal jurisdiction bears the burden of establishing [standing] elements.").

The standing inquiry is "especially rigorous when," as true here, "reaching the merits of the dispute would force us to decide whether an action taken by one of the other two branches of the Federal Government was unconstitutional." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 408 (2013). Moreover, because AAPS was not itself "the object" of the challenged EUA, standing is "substantially more difficult to establish." *Lujan*, 504 U.S. at 562. AAPS simply cannot meet this fundamental burden.

#### A. AAPS lacks associational standing.

AAPS does not allege any direct injury to the organization itself, so its standing depends solely upon alleged harms to its members. *See* Compl., PageID.1 ("AAPS brings this action on behalf of its members . . . ."); PI Mem., PageID.302 ("AAPS has associational standing because its members have standing . . . ."); *see also Sierra Club*, 793

F.3d at 661. To have associational standing, AAPS must establish that "(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). AAPS cannot satisfy the "Article III necessity" of showing that any of its members individually would have standing, which compels dismissal of this suit. *United Food & Com. Workers Union Local 751 v. Brown Grp., Inc.*, 517 U.S. 544, 555 (1996).

**1. AAPS has not identified any injured members to qualify for associational standing.**

The associational standing doctrine requires that AAPS "*identify* members who have suffered the requisite harm." *Summers v. Earth Island Inst.*, 555 U.S. 488, 499 (2009) (emphasis added). Moreover, the allegations related to that "named member"—not those of unnamed members—must be sufficient to establish standing for each claim and form of requested relief. *Waskul v. Washtenaw Cty. Cmty. Mental Health*, 900 F.3d 250, 253, 257-58 (6th Cir. 2018). No unnamed members are entitled to relief if the named member lacks standing to press a claim or seek relief. *See id.*

Here, the only member AAPS purports to identify is an anonymous "Dr. John Doe." *See* PI Mem., PageID.323. Dr. Doe did not file a declaration or affidavit. Instead, his alleged experience is relayed third-hand in a few sentences of an unverified complaint, *see* Compl., PageID.19, and by an AAPS executive's declaration, *see* Snavely Decl., ECF No. 9-2, PageID.355-56. These anonymous allegations offend both associational standing doctrine and basic pleading standards.

Under the Supreme Court's associational standing doctrine, AAPS must "make *specific* allegations establishing that at least one *identified* member had suffered or would suffer harm." *Summers*, 555 U.S. at 498 (emphases added); *see FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 235 (1990) (ruling that an affidavit which "fails to identify the

individuals" who allegedly were injured "falls short of establishing" standing). A John Doe allegation does not satisfy the Supreme Court's requirement for specific identification of a member who has standing to sue.

Except in limited circumstances and with leave of court, federal pleading standards generally require naming individual parties. *See Doe v. Porter*, 370 F.3d 558, 560 (6th Cir. 2004) (citing Fed. R. Civ. P. 10(a)). Because AAPS's associational standing rests entirely upon Dr. Doe's individual standing, the need for identification applies equally as if Dr. Doe were a plaintiff himself. Yet AAPS has not shown that Dr. Doe can and should remain anonymous—let alone received permission of the Court to so do. This failure is "fatal" to AAPS's attempt to proceed. *See Citizens for a Strong Ohio v. Marsh*, 123 F. App'x 630, 637 (6th Cir. 2005). With no purportedly identified member other than Dr. Doe, AAPS necessarily lacks standing.

**2. Even considering the allegations about Dr. Doe, AAPS cannot establish standing.**

Even if considered, the allegations about Dr. Doe are insufficient to confer standing upon AAPS. To satisfy the "irreducible constitutional minimum," *Lujan*, 504 U.S. at 560, AAPS "must show that one of its named members '(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.'" *Waskul*, 900 F.3d at 255 (quoting *Spokeo*, 136 S. Ct. at 1547).

As the only purportedly identified member, Dr. Doe must have standing for each claim and form of relief. *See, e.g.*, *Waskul*, 900 F.3d at 253, 257-58. But the record contains only eight references to Dr. Doe—five in the complaint, *see* PageID.19, and three in an AAPS executive's declaration that duplicates the complaint, *see* PageID.355-56—none of which contain anything more than barebones allegations of harm from the EUA. These eight references are too slender a reed to support standing.

Dr. Doe has not suffered a "legal harm" as a result of the EUA such that he may challenge it. *Fednav, Ltd. v. Chester*, 547 F.3d 607, 618 (6th Cir. 2008). Before, during, and after the EUA's existence, federal law did not prohibit Dr. Doe from prescribing hydroxychloroquine to a patient. Dr. Doe's purported fear of retaliation by a *state* medical board is, at best, speculative and subjective, and certainly not traceable to the *federal* defendants here. Dr. Doe also alleges no violation of his own rights to equal protection and freedom of association—AAPS does not show, for instance, that Dr. Doe is elderly or unable to attend conventions as a result of the government's actions. Because Dr. Doe has not adequately alleged "an injury-in-fact sufficient to confer standing in [his] own right," AAPS too lacks standing. *Nat'l Rifle Ass'n of Am. v. Magaw*, 132 F.3d 272, 295 (6th Cir. 1997).

**a. The EUA neither inhibited Dr. Doe's ability to prescribe hydroxychloroquine nor impaired the commercial supply.**

Dr. Doe must establish an injury in fact "that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Spokeo*, 136 S. Ct. at 1548 (quoting *Lujan*, 504 U.S. at 560). Dr. Doe claims two injuries: (1) an unspecified inability "to successfully prescribe a full regimen" of hydroxychloroquine allegedly due to the EUA; and (2) a "fear [of] retaliation . . . by state medical boards based on the . . . EUA." Compl., PageID.19. Neither claim holds up under scrutiny.

*First*, Dr. Doe's conclusory allegation about an inability to prescribe hydroxychloroquine is belied by AAPS's own allegations and the Sixth Circuit. Hydroxychloroquine is an FDA-approved drug. Compl., PageID.2; EUA, PageID.475. AAPS itself acknowledges that physicians prescribe FDA-approved drugs for unapproved uses (referred to as "off-label" uses), if the prescriber determines it is medically appropriate for particular patients. *See* Compl., PageID.6. The Sixth Circuit has addressed this issue too, observing that "[a]bsent state regulation, once a drug has been approved by the FDA, doctors may prescribe it for indications and in dosages

other than those expressly approved by the FDA." *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 505 (6th Cir. 2006); *see Planned Parenthood Sw. Ohio Region v. DeWine*, 696 F.3d 490, 495–96 (6th Cir. 2012) ("[o]nce a drug has been approved," FDA "does not ban" physicians from prescribing a drug for an unapproved, or so-called "off-label use").

The EUA did not alter this status quo. By its plain terms, the EUA applied solely to hydroxychloroquine "distributed from the [Stockpile] to public health authorities for response to the COVID-19 pandemic." EUA, PageID.477. It did *not* apply to or restrict physicians from prescribing hydroxychloroquine obtained on the commercial market.

The EUA's revocation also did not impact Dr. Doe's ability to prescribe hydroxychloroquine for an off-label use. *See Planned Parenthood Cincinnati*, 444 F.3d at 505. Hydroxychloroquine remains an FDA-approved drug that "can be distributed in interstate commerce." EUA Revocation, PageID.369. AAPS recognizes this point, quoting the HHS Secretary's statement that "[i]f a doctor wishes to prescribe [hydroxychloroquine], working with a patient, they may prescribe it for any purpose they wish to do so." Snavely Decl., PageID.357.[4] For FDA's part, when announcing the revocation, the agency acknowledged that "FDA approved products may be prescribed by physicians for off-label uses if they determine it is appropriate for treating their patients, including during COVID." News Release, FDA, *Coronavirus (COVID-19)*

[4] AAPS asserts that another HHS website made a contradictory statement, *see* Snavely Decl., PageID.357-58, but the website itself refers only to hydroxychloroquine "donated to HHS/[Office of the Assistant Secretary for Preparedness and Response's] Strategic National Stockpile" and acknowledges that the drug remains FDA-approved, HHS, Assistant Secretary for Preparedness and Response, *Chloroquine and hydroxychloroquine*, https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/hydroxychloroquine.aspx (last reviewed June 26, 2020).

*Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine* (June 15, 2020).[5]

Under federal law, neither the EUA nor its revocation prohibited Dr. Doe from prescribing hydroxychloroquine to a patient for COVID-19. Thus, Dr. Doe's barebones and conclusory allegation to the contrary does not establish an injury that is "actual" or "concrete," in the sense that it is "'real,' and not 'abstract.'" *Crawford v. U.S. Dep't of Treasury*, 868 F.3d 438, 453 (6th Cir. 2017) (quoting *Spokeo*, 136 S. Ct. at 1548). Indeed, Dr. Doe has suffered no injury that "actually exist[s]." *Spokeo*, 136 S. Ct. at 1548.

*Second*, Dr. Doe alleges a "fear" of unspecified future "retaliation" by "*state* medical boards" and the Federation of State Medical Boards ("FSMB"). Snavely Decl., PageID.355-56 (emphasis added); Compl., PageID.19. The Supreme Court has "repeatedly reiterated that threatened injury must be *certainly impending* to constitute injury in fact, and that allegations of *possible* future injury are not sufficient." *Clapper*, 568 U.S. at 409 (alteration and quotations omitted). Yet again Dr. Doe's alleged injury is insufficiently pleaded and also not traceable to defendants.

Dr. Doe fails to "clearly . . . allege facts," *Spokeo*, 136 S. Ct. at 1547, to show that any action by his own governing medical board is "certainly impending," *Clapper*, 568 U.S. at 409. Dr. Doe supposedly practices medicine in Michigan. *See* Compl., PageID.19. Yet he conspicuously cites no actions by the Michigan Board of Medicine that threaten him (or anyone) with injury of any kind. All he alleges is an undifferentiated fear of unspecified retaliation for an unknown reason by an unidentified medical board. This "abstract, hypothetical, and speculative" fear is insufficient to confer standing. *Nat'l Rifle Ass'n*, 132 F.3d at 294.

[5] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and (last revised June 15, 2020).

Dr. Doe's "fear" of FSMB, based on a "directive made to state medical boards," is also insufficiently pleaded. Compl., PageID.19. Although the complaint alleges that FSMB "directs state medical boards," *id.*, PageID.18, FSMB simply "serves as the voice for state medical boards, supporting them through education, assessment, research and advocacy," FSMB Statement, PageID.497. As AAPS itself alleges, state medical boards—not their representative advocacy group—"wield complete authority over licenses to practice medicine." Compl., PageID.18.

Moreover, the FSMB statement upon which AAPS relies does not apply to Dr. Doe. FSMB expressed concern about physicians "inappropriately prescribing medications," including hydroxychloroquine, "to prevent or treat COVID-19 *for themselves or their family members*" and advised physicians to "avoid prescribing for themselves or their family members." FSMB Statement, PageID.496 (emphasis added); *see* Compl., PageID.18. Even if FSMB had authority over Dr. Doe's practice (which it does not), Dr. Doe does not allege that he wishes to prescribe the drug for himself or a family member. Thus, FSMB's statement could not threaten Dr. Doe, let alone establish an injury for standing purposes.

Even assuming that Dr. Doe adequately alleged a fear of retaliation by a powerless advocacy group or an unspecified *state* medical board, such an injury is not traceable to the *federal* defendants. AAPS "cannot rely on speculation about the unfettered choices made by independent actors not before the court" to establish standing, as it tries to do here. *Clapper*, 568 U.S. at 414 n.5 (quotation omitted).

State medical boards are independent institutions and are not controlled by the federal defendants. *See Planned Parenthood Cincinnati*, 444 F.3d at 505 (regulating "the practice of medicine . . . is the exclusive realm of individual states"); Compl., PageID.18 (alleging state medical boards "wield complete authority over licenses to practice medicine"). Neither the EUA nor any federal statute or regulation dictates the activities of any state medical board related to the prescribing of hydroxychloroquine for COVID-

19. Thus, Dr. Doe's fear of injury is not traceable to the EUA and cannot establish standing in this case. *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976) (federal court may only "redress injury that fairly can be traced to the challenged action of the defendant, and not injury that results from the independent action of some third party not before the court").

**b. The EUA caused no injury to Dr. Doe's constitutional rights.**

As the only purportedly identified member of AAPS, Dr. Doe must have standing "for each claim [AAPS] seeks to press." *DaimlerChrysler*, 547 U.S. at 335; *see Waskul*, 900 F.3d at 253, 257-58. Just as Dr. Doe lacks standing to bring an APA claim, he also lacks standing to assert an equal protection claim under the Fifth Amendment or a freedom of association claim under the First Amendment because Doe is not "himself among the injured." *Lujan*, 504 U.S. at 563.

A plaintiff bringing a Fifth Amendment claim against the federal government based on the guarantee of equal protection must show that "the government treated the *plaintiff*" differently than similarly situated persons. *Ctr. for Bio-Ethical Reform, Inc. v. Napolitano*, 648 F.3d 365, 379 (6th Cir. 2011) (emphasis added). Dr. Doe does not allege that the EUA treats physicians like himself differently than other physicians, nor could he because the EUA plainly did not. Moreover, Dr. Doe does not allege that he suffered any of the equal protection violations AAPS alleges that its members suffered, *i.e.*, personally desiring to take hydroxychloroquine but being prohibited from doing so, being elderly, or wanting to attend in-person religious services. In fact, there are no allegations at all connecting Dr. Doe to the equal protection claim in the complaint. *See* Compl., PageID.21.

Likewise, Dr. Doe cannot support AAPS's First Amendment freedom of association claim, which is premised upon members' alleged inability to take hydroxychloroquine and gather in groups. *See* Compl., PageID.22. Dr. Doe does not allege that he himself

wishes to take hydroxychloroquine or wants to attend an AAPS gathering or a political convention. Thus, Dr. Doe has not even asserted equal protection and freedom of association claims, let alone alleged facts to establish Article III standing for them. *See Lujan*, 504 U.S. at 563.

**c. Dr. Doe cannot bring a generalized challenge to HHS's deployment of the Stockpile.**

At bottom, this suit is no more than AAPS's improper attempt "to employ a federal court as a forum in which to air . . . generalized grievances about the conduct of government." *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 483 (1982). "[W]hen the asserted harm is a 'generalized grievance' shared in substantially equal measure by all or a large class of citizens, that harm alone normally does not warrant exercise of jurisdiction." *Warth v. Seldin*, 422 U.S. 490, 499 (1975). Rather, "such suits"—including this one—"do not present constitutional 'cases' or 'controversies.'" *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 127 n.3 (2014).

For example, AAPS' stated purpose is to vindicate "the ability of President Donald Trump to make available to the public the same safe medication that he and other world leaders have successfully taken for themselves." PI Mem., PageID.295; *see* Compl., PageID.1-2. This purpose is wholly unrelated to Dr. Doe (or AAPS) "'*personally* [having] suffered some actual or threatened injury'" from the EUA. *Crawford*, 868 F.3d at 453 (quoting *Valley Forge*, 454 U.S. at 472) (emphasis in original). Rather, it would exceed a federal court's authority and improperly "intrude upon" the Executive Branch's power. *Spokeo*, 136 S. Ct. at 1547.

Through its single-minded focus on the Stockpile, AAPS perplexingly ignores—and simultaneously highlights—the commercial availability of hydroxychloroquine. AAPS laments that the Stockpile's supply of the drug has not yet been made available for "public access." PI Mem., PageID.297. Yet AAPS also states that the drug is in

"plentiful supply," is "easy-to-manufacture," and "scarcity" is not an issue. Compl., PageID.15-16; *see also id.*, PageID.17-18 (alleging that manufacturers can "produce a million new doses of [hydroxychloroquine] daily"); Orient Decl., ECF No. 9-1, PageID.347 (hydroxychloroquine "is very inexpensive, costing less than a dollar a dose"). Again, AAPS's own statements reveal that it sued to air its views about the management of hydroxychloroquine donated to the Stockpile and not due to any injury suffered by a purported lack of access to the drug. But "[s]tanding requires more" than a keen interest in the Stockpile. *Trump v. Hawaii*, 138 S. Ct. 2392, 2416 (2018).

In any event, Dr. Doe has no legally protected interest in the disposition of supplies from the Stockpile. *See Risser v. Thompson*, 930 F.2d 549, 551 (7th Cir. 1991) ("Ordinarily, a person lacks standing to complain about the deprivation of something in which he has no legally protected interest."); *see also Phillips v. DeWine*, 841 F.3d 405, 417 (6th Cir. 2016). AAPS identifies no legal authority establishing a private right to demand distribution of supplies in the Stockpile. Rather, all items maintained in the Stockpile are property of the federal government and deployment decisions are committed to HHS's "discretion." 42 U.S.C. §§ 247d-6b(a)(1), (a)(3)(G). AAPS can no more dictate the deployment of hydroxychloroquine from the Stockpile than a person off the street with a headache can demand Tylenol from a VA hospital. With no legally protected interest, Dr. Doe and consequently AAPS cannot demand relief from the Stockpile. *See Phillips*, 841 F.3d at 417; *Sheldon v. Vilsack*, 538 F. App'x 644, 653-54 (6th Cir. 2013) (holding "no protected legal interest" in a "process that the Secretary was authorized, but not obligated, to establish").

Moreover, AAPS's requested relief—ordering HHS to distribute all hydroxychloroquine in the Stockpile "for the benefit of the public," and prohibiting HHS from "impeding the distribution, sale, or purchase of [hydroxychloroquine] by adult members of the public," Compl., PageID.23-24—plainly signals the generalized nature of AAPS's grievance. By "seeking relief that no more directly and tangibly

benefits [Dr. Doe or AAPS] than it does the public at large," AAPS "does not state an Article III case or controversy." *Lujan*, 504 U.S. at 573-74.

**B. AAPS lacks third-party standing to assert claims on behalf of unknown patients.**

The Complaint cursorily mentions claims brought on behalf of AAPS members' patients. *See* Compl., PageID.1. To the extent AAPS seeks to assert standing on behalf of its members' patients, AAPS fails to do so.

Generally, a plaintiff "must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." *Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004) (quoting *Warth*, 422 U.S. at 499). Otherwise, "the courts might be called upon to decide abstract questions of wide public significance even though other governmental institutions may be more competent to address the questions and even though judicial intervention may be unnecessary to protect individual rights." *Kowalski*, 543 U.S. at 129 (internal quotation omitted). Although the Supreme Court has "not looked favorably upon third-party standing," *Kowalski*, 543 U.S. at 130, "certain, limited exceptions" apply, *Powers v. Ohio*, 499 U.S. 400, 410 (1991).

To bring claims on behalf of third-party patients, AAPS must satisfy "three important criteria." *Powers*, 499 U.S. at 411; *see Moody v. Mich. Gaming Control Bd.*, 847 F.3d 399, 402 (6th Cir. 2017). First, AAPS "must have suffered an injury in fact, thus giving [it] a sufficiently concrete interest in the outcome of the issue in dispute." *Powers*, 499 U.S. at 411 (quotations omitted). Second, AAPS "must have a close relation to the third party." *Id.* And third, "there must exist some hindrance to the third party's ability to protect his or her own interests." *Id.* None of these criteria are met here.

As discussed above, AAPS has failed to establish that it or Dr. Doe has actually suffered an injury in fact. Indeed, this case epitomizes the Supreme Court's caution against liberally allowing third-party standing. Questions "of wide public significance" about hydroxychloroquine's effectiveness against COVID-19 and the Stockpile's

deployment were entrusted by Congress to officials at FDA and HHS. *Kowalski*, 543 U.S. at 129. Judicial intervention is "unnecessary to protect individual rights" because the EUA did not thwart a physician, who, exercising medical judgment, concluded that prescribing hydroxychloroquine was appropriate for her patients with COVID-19. *Id.*

AAPS also has not established that it has a close relationship with the alleged third-party patients. The record is devoid of specific allegations about patients of AAPS members who affirmatively want to take hydroxychloroquine and have been prevented from doing so by the EUA. Thus, a critical gap exists between AAPS's suit and any third-party patient's actual desire to sue the federal defendants. Lastly, to the extent any patients would have the motivation and standing to sue HHS, AAPS has not shown any hindrance to patients' ability to assert their own rights.

**II. This case must be dismissed as moot.**

Even assuming an Article III case or controversy existed when this case was filed, the EUA has been revoked and the case is now moot. "A suit becomes moot when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *Chafin v. Chafin*, 568 U.S. 165, 172 (2013) (cleaned up). If post-filing events "deprive the court of the ability to give meaningful relief, then the case is moot and must be dismissed." *Ailor v. City of Maynardville*, 368 F.3d 587, 596 (6th Cir. 2004) (quotation omitted). Because the EUA has been revoked, AAPS cannot obtain meaningful relief and lacks a legally cognizable interest in persisting with this suit.

Beginning with the APA claim, the only final agency action challenged in the complaint is the issuance of the EUA. *See* Compl., PageID.22. Given that AAPS's claims solely address the EUA's limitation on the use of hydroxychloroquine from the Stockpile for hospitalized patients with COVID-19 who lacked access to a clinical trial, the maximum relief available to AAPS under the APA would have been vacatur of the challenged aspect of the EUA and remand to FDA. *See* 5 U.S.C. § 706 (court shall "set

aside" agency action found to be unlawful). The EUA, however, has already been revoked. The Court cannot vacate what no longer exists. *See Kiser v. Kamdar*, 752 F. App'x 272, 274 (6th Cir. 2018) ("[A] court order opining on a *repealed* [agency action] would have no effect in the real world."); *Ailor*, 368 F.3d at 600 (holding case was moot when "the injuries suffered in the complaint had been remedied by events subsequent to the filing of the lawsuit, with no showing of a reasonable likelihood of recurrence").[6]

AAPS decided not to address this change in circumstances and did not amend its complaint. Instead, AAPS attempts to expand the scope of this lawsuit and challenge the EUA's revocation through its preliminary injunction motion. *See* PI Mem., PageID.327. But AAPS cannot amend its complaint in a brief "or ask the court to consider new allegations (or evidence) not contained in the complaint." *Bates v. Green Farms Condo. Ass'n*, 958 F.3d 470, 483 (6th Cir. 2020).

Because they are premised upon the EUA as the source of the violation, AAPS's equal protection and freedom of association claims are equally moot. *See* Compl., PageID.21-22. Even if AAPS had standing to bring and adequately pleaded a viable

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[6] Although voluntary cessation of challenged conduct does not automatically moot a case, "the burden in showing mootness is lower when it is the government that has voluntarily ceased its conduct." *Speech First, Inc. v. Schlissel*, 939 F.3d 756, 767 (6th Cir. 2019). Here, FDA acted pursuant to its statutory obligation to "periodically review the circumstances and the appropriateness of an" EUA, and its authority to revoke the EUA if the issuance criteria are no longer satisfied. 21 U.S.C. § 360bbb-3(g)(1)-(2). The decision was made as "part of a collaborative, [U.S. Government]-interagency effort to rapidly respond to this continuously evolving public health emergency." EUA Revocation, PageID.368. And it was driven by reviews conducted by "FDA scientific staff" of newly-available data and "new analyses of information known at the time of the initial authorization." *Id.*, PageID.371; *see Hanrahan v. Mohr*, 905 F.3d 947, 961 (6th Cir. 2018) (holding case was moot, in part, because "new policies were formally promulgated and approved by [high-ranking decisionmaker] after a lengthy internal process"). The record also "is devoid of any expressed intention by" FDA to reissue the EUA challenged by AAPS. *Ky. Right to Life, Inc. v. Terry*, 108 F.3d 637, 645 (6th Cir. 1997). Accordingly, the revocation "means there is no longer a live case or controversy." *Hanrahan*, 905 F.3d at 963.

equal protection claim, the EUA's revocation eliminated any alleged equal protection violation and need for relief. *See Heckler v. Matthews*, 465 U.S. 728, 740 n.8 (1984) ("[W]e have often recognized that the victims of a discriminatory government program may be remedied by an end to preferential treatment for others."). Likewise, while the EUA did not restrict AAPS's members' ability to associate — *i.e.*, they remained free to associate in the same way as anyone else—revocation of the EUA eliminated the government action that AAPS claims caused the First Amendment violation.

Although AAPS continues to press its views about hydroxychloroquine and the Stockpile in its preliminary injunction motion, none of those views are "embedded in any actual controversy about [AAPS's] particular *legal* rights," *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013) (quotation omitted and emphasis added), and no role remains for the Court. Accordingly, this case "must be dismissed as moot." *Hanrahan*, 905 F.3d at 963 (quoting *Genesis Healthcare Corp. v. Symczyk*, 569 U.S. 66, 72 (2013)).

## III. The complaint must be dismissed for failure to state a claim.

Even if AAPS had standing to bring this action and the EUA's revocation had not rendered it moot, the complaint still must be dismissed for failure to state a claim. "[F]ocus[ing] only on the allegations in the pleadings," as a court must when evaluating a motion to dismiss, reveals no well-pleaded claims for relief. *Bates*, 958 F.3d at 483. The APA claim is excepted by statute from judicial review. The freedom of association and equal protection claims equally fall short.

### A. AAPS fails to state an APA claim for which relief can be granted.

AAPS alleges that the EUA's scope of authorization—*i.e.*, treatment of patients hospitalized with COVID-19 for whom participation in a clinical trial is not available or feasible—is arbitrary and capricious, in excess of statutory authority, and contrary to section 1557 of the Affordable Care Act ("ACA"). *See* Compl., PageID.22; *see also* 5 U.S.C. § 706(2). These allegations fail to state an APA claim because decisions regarding

EUAs are committed to agency discretion by law, FDA acted well within its statutory authority, and section 1557 of the ACA does not apply to the EUA or the Stockpile. *See, e.g.*, *Berry v. U.S. Dep't of Labor*, 832 F.3d 627, 632 (6th Cir. 2016) (holding that challenge to "the availability of judicial review under the APA is properly analyzed under Federal Rule of Civil Procedure 12(b)(6)").

**1. FDA's decisions about the EUA are committed to agency discretion and excepted from APA review.**

The APA excepts from judicial review "agency action [that] is committed to agency discretion by law." 5 U.S.C. § 701(a)(2). Congress did just that in the EUA statute.

That statute provides that "[a]ctions under the authority of this section by the Secretary [of HHS] or by the Secretary of Defense are committed to agency discretion." 21 U.S.C. § 360bbb-3(i). Congress's choice to echo the language of 5 U.S.C. § 701(a)(2) inexorably leads to one conclusion: Actions pursuant to the authority granted in 21 U.S.C. § 360bbb-3 are committed to agency discretion and not subject to judicial review under the APA. *See Lamie v. U.S. Tr.*, 540 U.S. 526, 534 (2004) ("It is well established that when the statute's language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms." (internal quotations omitted)).

FDA's decision to issue an EUA and its determination of the appropriate limits of that authorization were expressly made "under the authority of" 21 U.S.C. § 360bbb-3. *See* EUA, PageID.474-79. As such, the Court must give effect to the language in section 360bbb-3(i) that plainly "expresses Congress' intent," *United States v. Ron Pair Enters.*, 489 U.S. 235, 241 (1989), and hold that APA review is unavailable here, *see Farkas v. United States*, 744 F.2d 37, 39 (6th Cir. 1984) (construing statutory provision that left certain actions "committed to agency discretion for purposes of section 701(a)(2) of title 5" to mean agency's "substantive decisions" were "insulated from judicial review").

Although the plain meaning of 21 U.S.C. § 360bbb-3(i) is dispositive, the statute's purpose and structure corroborate the conclusion that HHS's actions related to an EUA are committed to agency discretion. *See Webster v. Doe*, 486 U.S. 592, 600-01 (1988) (considering statute's purpose and structure in finding actions were committed to agency discretion). Section 360bbb-3 was part of the larger Project BioShield Act of 2004. P.L. 108-276, 118 Stat. 835 (2004). The Project BioShield Act provided for the development and acquisition of new medical countermeasures against chemical, biological, radiological, or nuclear agents that might be used against the United States, and included various new authorities to protect the United States from harm caused by such agents. *Id.* at 835. Congress provided EUA authority to FDA specifically to "streamlin[e] . . . the approval process of countermeasures." 118 Stat. at 835.

The statute is also permeated with grants of discretion at key steps of the process. The Secretary "may" declare "that the circumstances exist justifying" an EUA, 21 U.S.C. § 360bbb-3(b)(1); "may" issue an EUA, *id.* §§ 360bbb-3(a)(1), (c); "may" place "conditions on an authorization" that are "necessary and appropriate to protect the public health," *id.* § 360bbb-3(e)(1)(B); and "may revise or revoke" an EUA, *id.* § 360bbb-3(g)(2); *see Kingdomware Techs., Inc. v. United States*, 136 S. Ct. 1969, 1977 (2016) (noting that "the word 'may' . . . implies discretion"). Thus, the statute "fairly exudes deference to" HHS, *Webster*, 486 U.S. at 600, and does not reflect a desire by Congress to make the Department's substantive decisions reviewable. Accordingly, AAPS's claim that the scope of the EUA is arbitrary and capricious is not subject to judicial review.[7]

[7] If the Court denies this motion to dismiss, FDA will defend its EUA decision on the merits. The Court's "narrow" review would occur "under the deferential 'arbitrary and capricious' standard" in 5 U.S.C. § 706(2)(A) and in light of the administrative record. *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2569 (2019) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). When as here, FDA has made a "scientific determination" about the propriety of an EUA that is "within its area of special expertise," "a reviewing court must generally be at its most

**2. FDA acted consistent with statutory authority when issuing the EUA.**

Notwithstanding the unreviewability of the EUA's substance under 5 U.S.C. § 701(a)(2), AAPS also fails to state a claim that the EUA exceeded FDA's authority. The EUA was issued fully in accordance with the authority granted by 21 U.S.C. § 360bbb-3, as is made plain in the document itself. *Compare* 21 U.S.C. § 360bbb-3(c) (criteria for issuance), *with* EUA, PageID.475-46 (explaining why criteria are satisfied).

Nonetheless, AAPS alleges that FDA lacked statutory authority "to limit access to a drug based on the patient's ability to participate in a clinical trial." Compl., PageID.22; *see* PI Mem., PageID.330. Just as AAPS overlooked the express statutory commitment to agency discretion, it now overlooks the express authorization to establish, in FDA's discretion, the scope and conditions of an EUA. *See* 21 U.S.C. § 360bbb-3(d), (e)(1)(B)(2), (e)(2). Thus, AAPS cannot plausibly allege that the EUA's authorization for treatment of patients hospitalized with COVID-19 for whom a clinical trial was not available was contrary to or exceeded statutory authority. *Bates*, 958 F.3d at 480 (pleading that is "no more than conclusions" is "not entitled to the assumption of truth" (quotations omitted)).

Likewise, AAPS fails to plausibly allege that the EUA is unlawful because BARDA's former director is biased against hydroxychloroquine. *See* Compl., PageID.13, 22. Whatever AAPS believes to be that individual's personal views, AAPS cannot

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deferential." *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983). Moreover, FDA's complex balancing of the relative risks and benefits of using hydroxychloroquine to treat COVID-19 involved "predictions, within its area of special expertise, at the frontiers of science," which are entitled to great deference. *Balt. Gas & Elec.*, 462 U.S. at 103; *see Marsh v. Oregon Nat. Res. Council*, 490 U.S. 360, 378 (1989) ("an agency must have discretion to rely on the reasonable opinions of its own qualified experts"). But of course, this Court may not proceed to the merits without first resolving the jurisdictional deficiencies raised by this motion. *In re: 2016 Primary Election*, 836 F.3d 584, 587 (6th Cir. 2016).

escape the fact that FDA, not BARDA, was the decisionmaker. *See* EUA, PageID.480 (EUA issued by FDA's Chief Scientist).[8]

Finally, AAPS's allegation that the EUA violates section 1557 of the Affordable Care Act, 42 U.S.C. § 18116, by discriminating against the elderly, *see* Compl., PageID.22, fails because that provision does not apply to the EUA or the Stockpile. Section 1557 prohibits discrimination in certain "health program[s] or activit[ies]" on the grounds prohibited under other nondiscrimination statutes, including the Age Discrimination Act of 1975 ("ADA"). 42 U.S.C. § 18116(a). The implementing regulations define "health program or activity" to mean "the provision or administration of health-related services, health-related insurance coverage, or other health-related coverage, and the provision of assistance to individuals in obtaining health-related services or health-related insurance coverage." 45 C.F.R. § 92.4.[9]

The EUA and the Stockpile fall outside that definition because they do not provide or administer health-related services or health-related coverage. The EUA and the Stockpile do not prescribe or administer drugs, operate programs for the administration of drugs, or provide insurance coverage for drugs. At most, the Stockpile maintains medical supplies for distribution to public health authorities during public health emergencies, and an EUA authorizes the use of unapproved drugs or approved drugs for unapproved uses, which in turn can be provided or administered by healthcare

[8] Although AAPS named BARDA and its current director as defendants, it has not pleaded "factual content that allows the court to draw the reasonable inference that" BARDA and its director are "liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. AAPS does not allege that BARDA issued the EUA or that BARDA is a proper defendant for purposes of granting relief. Thus, at a minimum, AAPS has failed to state a claim against BARDA and its director, and both should be dismissed from this suit.

[9] HHS issued a final rule revising 45 C.F.R. Part 92 on June 12, 2020, which becomes effective on August 18, 2020, and is not applicable here.

entities; neither the Stockpile nor the EUA qualify as a "health program or activity."[10] For these reasons, AAPS's argument that Defendants violated section 1557 must fail.

**B. AAPS fails to state a claim under the First or Fifth Amendments.**

"The freedom to associate protects 'choices to enter into and maintain certain intimate human relationships' as well as 'associat[ion] for the purpose of engaging in those activities protected by the First Amendment.'" *Saieg v. City of Dearborn*, 641 F.3d 727, 741 (6th Cir. 2011) (quoting *Roberts v. United States Jaycees*, 468 U.S. 609, 617-18 (1984)). It is unclear whether AAPS seeks to assert a claim based on the right to maintain intimate relationships or to assemble "for the purpose of speaking." *U.S. Citizens Ass'n v. Sebelius*, 705 F.3d 588, 600 (6th Cir. 2013). Either way, AAPS fails to state a claim under the First Amendment.

AAPS did not "explain how its size, purpose, policies, selectivity, and congeniality establish that it has a protected right to intimate association." *U.S. Citizens*, 705 F.3d at 599. It likewise failed to show how the EUA itself "significantly burdens the group's expression" or "impairs [its] ability to engage in expressive conduct." *U.S. Citizens*, 705 F.3d at 600. AAPS has always remained free to state its views about the relative benefits of hydroxychloroquine. Any restrictions on public gatherings were the result of state and local directives, not the EUA. Because neither the EUA nor its revocation impacted

[10] Even if section 1557 applied, AAPS failed to exhaust administrative remedies as required by the ADA. *See Doe v. BlueCross BlueShield of Tenn., Inc.*, 926 F.3d 235, 239 (6th Cir. 2019) (holding that in section 1557 "by referring to four statutes, Congress incorporated the legal standards that define discrimination under each one"). The ADA expressly requires that before bringing an action in district court, an individual must exhaust administrative remedies by filing an administrative complaint with the appropriate Federal department or agency, which AAPS admittedly has not done. *See* 42 U.S.C. § 6104(e), (f); *BlueCross BlueShield*, 926 F.3d at 240 (Age Discrimination Act requires exhaustion of administrative remedies). Moreover, AAPS's ADA argument is premised on disparate impact, which as discussed below, it cannot show, and which has been questioned by the Sixth Circuit. *See BlueCross BlueShield*, 926 F.3d at 240 (noting "there is no reason to think the Age Discrimination Act of 1975 picks up [the disparate impact discrimination] standard of liability").

AAPS's freedom to associate, AAPS fails to plausibly state a First Amendment claim. *See Saieg*, 641 F.3d at 741 (holding that plaintiff's "freedom to associate has not been abridged in any way comparable to" examples such as where the government tries to "interfere with the internal organization or affairs of the group" or "seek[s] to impose penalties or withhold benefits from individuals because of their membership in a disfavored group").

Turning to the Fifth Amendment, "[t]o state an equal protection claim, [AAPS] must adequately plead that the government treated [it] 'disparately as compared to similarly situated persons and that such disparate treatment either burdens a fundamental right, targets a suspect class, or has no rational basis.'" *Ctr. for Bio-Ethical Reform, Inc.*, 648 F.3d at 379. AAPS concedes that rational basis review would apply, *see* Compl., PageID.21,[11] meaning "the governmental policy at issue will be afforded a strong presumption of validity and must be upheld as long as there is a rational relationship between the disparity of treatment and some legitimate government purpose," *Midkiff v. Adams Cty. Reg'l Water Dist.*, 409 F.3d 758, 770 (6th Cir. 2005) (quotations omitted). AAPS must either "negat[e] every conceivable basis which might support the government action" or "demonstrat[e] that the challenged government action was motivated by animus or ill-will." *Davis v. Prison Health Servs.*, 679 F.3d 433, 438 (6th Cir. 2012). It cannot.

At the outset, AAPS fails to plausibly demonstrate that the EUA disparately treated the elderly, Compl., PageID.21, by authorizing use of hydroxychloroquine from the Stockpile only for treating "adult and adolescent patients who weigh 50 kg or more hospitalized with COVID-19 for whom a clinical trial is not available, or participation is

[11] AAPS's claim that "[i]nherent in the constitutional right to attend religious services is a right to equal access to prophylactic and early treatment for a disease which may be transmitted during such services," Compl., PageID.21, is entirely without legal support and "near frivolous," *White v. United States*, 601 F.3d 545, 555 (6th Cir. 2010).

not feasible," EUA, PageID.477. Facially, the EUA treats all adult and adolescent patients equally, and AAPS alleges no facts showing a disparate impact on the elderly based on who received hydroxychloroquine under the EUA and who did not. *See Bates*, 958 F.3d at 480 (allegation must be supported "with enough pleaded facts" to make it plausible).

Otherwise, AAPS "alleges injury to nearly all Americans," *Ctr. for Bio-Ethical Reform*, 648 F.3d at 379, by claiming that the EUA should have made hydroxychloroquine from the Stockpile available to anyone regardless of whether the use would be for prophylaxis or for treatment of COVID-19, *see* Compl., PageID.21. But FDA had "facially legitimate reasons" for the EUA's conditions, showing a rational basis. *Rondigo, L.L.C. v. Twp. of Richmond*, 641 F.3d 673, 683 (6th Cir. 2011). During a pandemic of unprecedented proportion and in the face of no known treatments for COVID-19, FDA issued the EUA because it was reasonable to believe at that time that the drug may be effective in treating COVID-19 in hospitalized patients and the potential benefits of the drug outweighed the risks. EUA, PageID.475-76. The EUA also encouraged participation in clinical trials that could produce additional data to further inform FDA's risk benefit assessment. *Id.*; *see Midkiff*, 409 F.3d at 770-71 (affirming dismissal of equal protection claim for failure "to rebut the presumption of constitutionality of" challenged policy when rational basis was self-evident). AAPS's allegations "fall far short of making out a plausible claim of entitlement to relief" under the Fifth Amendment. *Rondigo*, 641 F.3d at 684.

**IV. AAPS is not entitled to a preliminary injunction.**

Even if the Court does not immediately dismiss this case, at a minimum, it should deny AAPS's motion for a preliminary injunction. AAPS's motion is "extraordinary" in kind, *Winter*, 555 U.S. at 24, and extraordinary in fact. "The purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the

merits can be held." *Hudson v. Caruso*, 748 F. Supp. 2d 721, 724 (W.D. Mich. 2010) (quoting *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981)). AAPS, however, seeks to short-circuit the process and obtain, among other things, immediate public distribution of hydroxychloroquine from the Stockpile. *Compare* Compl., PageID.23-24, *with* PI Mot., PageID.67-68.

More than that, AAPS impermissibly asks this Court to order "HHS and FDA to retract" certain June 16, 2020, statements about hydroxychloroquine—none of which are referenced in the complaint. PI Mot., PageID.67. AAPS has "no grounds to seek an injunction pertaining to allegedly impermissible conduct not mentioned in [its] original complaint." *Colvin v. Caruso*, 605 F.3d 282, 300 (6th Cir. 2010). And it cannot circumvent amending its complaint by incorporating new allegations through its preliminary injunction motion. *See Bates*, 958 F.3d at 483.

The relevant factors do not support preliminary relief here. *First*, for the reasons discussed above, AAPS has no likelihood of success on the merits and therefore is not entitled to an injunction. *Michigan State AFL-CIO v. Miller*, 103 F.3d 1240, 1249 (6th Cir. 1997).

*Second*, "[t]o demonstrate irreparable harm," AAPS must show that absent emergency relief, it "will suffer actual and imminent harm rather than harm that is speculative or unsubstantiated." *Abney v. Amgen, Inc.*, 443 F.3d 540, 552 (6th Cir. 2006) (quotations omitted). As discussed above, AAPS has not adequately shown that it or any of its members have suffered any actual harm, let alone harm caused by the defendants here that justifies relief. Thus, AAPS has not made the "clear showing" of irreparable harm necessary for preliminary relief. *Winter*, 555 U.S. at 22.

*Third*, the factors of "harm to the opposing party and weighing the public interest . . . merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). Indeed, the Court must "pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Winter*, 555 U.S. at 24; *see Wilson*

*v. Williams*, 961 F.3d 829, 844 (6th Cir. 2020) (vacating preliminary injunction because, among other reasons, "the district court gave scant attention to the harms the [agency] argued would result from the injunction"). AAPS's requested injunction would have a dramatic and deleterious effect on HHS's authority to respond to public health emergencies.

AAPS would override the discretionary decisions of public health officials during an unprecedented emergency and make hydroxychloroquine from the Stockpile publicly available without restriction. Congress did not afford private entities that right. *See Va. Petroleum Jobbers Ass'n v. Fed. Power Comm'n*, 259 F.2d 921, 925 (D.C. Cir. 1958) ("In litigation involving the administration of regulatory statutes designed to promote the public interest, . . . [t]he interests of private litigants must give way to the realization of public purposes."). HHS, *not* AAPS, has the authority to determine how to deploy the Stockpile to protect the public health. *See* 42 U.S.C. § 247d-6b(a)(3)(G). FDA, *not* AAPS, has the authority to determine whether, and under what conditions, an EUA should issue. *See* 21 U.S.C. § 360bbb-3(b)-(c); *cf. Abney*, 443 F.3d at 553 (affirming denial of preliminary injunction because "[t]he public has a strong interest in ensuring that the FDA rather [than] individual doctors has the power to decide what drugs meet baseline levels of safety and efficacy"). The equities certainly counsel against a preliminary injunction that "would dramatically disrupt—rather than preserve—the status quo" by allowing AAPS to wrest control of responding to a public health emergency from the very officials Congress charged with that duty. *Gale v. O'Donohue*, 751 F. App'x 876, 885 (6th Cir. 2018).

During times of global pandemic, the Constitution "principally entrusts '[t]he safety and the health of the people' to the politically accountable officials . . . 'to guard and protect.'" *S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1613 (2020) (Roberts, C.J., concurring in denial of application) (quoting *Jacobson v. Massachusetts*, 197 U.S. 11, 38 (1905)). These officials' actions in "areas fraught with medical and scientific

uncertainties, . . . should not be subject to second-guessing" in litigation by those lacking "the background, competence, and expertise to assess public health" and who are "not accountable to the people." *Id.* at 1613-14 (quotations omitted). AAPS's preliminary injunction motion must be denied.

## CONCLUSION

This Court should grant Defendants' motion to dismiss for lack of jurisdiction and failure to state a claim. Even if the Court does not grant the motion to dismiss, it should deny AAPS's motion for a preliminary injunction.

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Respectfully submitted,

s/ James W. Harlow
JAMES W. HARLOW
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
PO Box 386
Washington, DC 20044-0386
(202) 514-6786
(202) 514-8742 (fax)
James.W.Harlow@usdoj.gov

**CERTIFICATE OF WORD COUNT COMPLIANCE**

Pursuant to Local Civil Rule 7.2(b)(i), I hereby certify that this brief contains 10,662 words, as calculated by the word count function of Microsoft Word 2016.

July 10, 2020

s/ James W. Harlow
JAMES W. HARLOW

**CERTIFICATE OF SERVICE**

I hereby certify that this document, filed through the CM/ECF system, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

July 10, 2020

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